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10/751,056	01/02/2004	Gerianne Tringali DiPiano	FEM 104	1945

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EXAMINER	
KIM, JENNIFER M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,056	DIPIANO ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 13, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed August 13, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 1-7, and 9 under 35 U.S.C. 112, first paragraph (written description) is hereby expressly withdrawn in view of Applicants' persuasive argument.

The rejection of claims 1, 2, 4-7 and 9 under 35 U.S.C. 102(b) as being anticipated by Mauvais-Jarvis et al. (U.S.Patent No. 4,919,937) is being maintained for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to address the newly added limitations.

The rejection of claims 1-4 and 6-9 under 35 U.S.C. 102(b) as being anticipated by Ragavan et al. (U.S.Patent No. 5,993,856) is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 31-33 of U.S. Patent No. 5,993,856 is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 17 of U.S. Patent No. 6,652,874 B2 is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of U.S. Patent No. 6,416,778 B1 is being maintained for the reasons stated in the previous Office Action.

Applicants' amendment necessitated additional rejections presented in this Office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-5 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the " **a specific drug formulation (e.g. drugs set forth in claims 6-8)** comprising a **specific penetration enhancer**" (see page 9 C of the specification), does not reasonably provide enablement for the "**a drug formulation comprising penetration enhancer**". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

2. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a drug formulation comprising a drug in an amount effective to provide relief from disease or disorder of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote deliver of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic. The nature of the invention is extremely complex in that it encompasses a drug formulation comprising **any drug with any penetration enhancer** that would provide relief from disease or disorders of the breast.

Breath of the Claims: The complex of nature of the claims are greatly exacerbated by breath of the claims. The claims encompass a drug formulation comprising a drug and a penetration enhancer which have potentially many different physical and chemical characteristic compatibility, that need to considered in a formulation. Each of which may or may not be addressed by the administration of the claimed combinations.

Guidance of the Specification: The guidance given by the specification as to how one would choose a drug or a penetration enhancer to prevent physical/chemical incompatibility is minimal. All of the guidance provided by the specification is directed towards a formulation comprising specific drug and a specific penetration enhancer.

Working Examples: All of the working examples provided by the specification are directed toward a formulation comprising a specific drug and a specific penetration enhancer.

State of the Art: While the state of the art is relatively high a formulation comprising a specific drug and a specific penetration enhancer (i.e. 4-Hydroxytamoxifen and triethanolamine), the state of the art with regard a formulation comprising **a drug with a penetration enhancer** is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a formulation similar to the claimed combination. The state of the art, Reed (WO 97/29735) teaches that there is problems with most known dermal penetration enhancers that they are often toxic, irritating or allergenic. Reed further teaches that theses difficulties remains with those dermal enhancers because the problem of irritation at the site of application has not been overcome. Reed further teaches some enhancers are toxic and unsuitable for application for the animal body. (page 3, lines 10-25). Moreover, the thermodynamic activity of a drug with vehicles can cause precipitation causing ceases percutaneous absorption. (pages 3-5, particularly, page 4, lines 1-5).

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual formulation comprising any drug with any penetration enhancer makes practicing the claimed invention unpredictable in terms of a formulation comprising any drug and any penetration enhancer.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate drug and a appropriate penetration enhancer and appropriate animal model system for one of the claimed combination and test the combination in the model system to determine whether or not the combination does not cause toxicity, irritation, allergy, precipitation and cease absorption. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard a formulation comprising a drug and a penetration enhancer with any drug with any penetration enhancer, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding a formulation comprising any drug with any penetration enhancer, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed

invention to formulate a formulation comprising a drug and a penetration enhancer.

Therefore, a drug formulation comprising a drug in an amount effective to provide relief from disease or disorder of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote deliver of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauvais-Jarvis et al. (U.S.Patent No. 4,919,937) of record evidenced by Oden (U.S.Patent No. 5,580,857).

Mauvais-Jarvis et al. teach **anti-estrogen drug** of 1-[4-(2-N-dimethylaminoethoxy)phenyl]-1(4-hydroxyphenyl)-2-phenylbut-1-(Z)-ene (also known as 4-hydroxytamoxifen) formulated in **aqueous alcoholic gel**. (abstract, claim 1).

Mauvais-Jarvis et al. teach that the drug can be administered percutaneously, **preferably topically** to a breast. (column 2, lines 29-32, column 3, lines 13-15, lines 52-57). Mauvais-Jarvis et al. observed that anti-estrogen drug, **4-hydroxytamoxifen**, in 60% strength **alcoholic solution** was applied on the skin overlying cancerous mammary tumors proved capable of passing through the cutaneous barrier and being taking up on the receptor molecules in these tumors. (column 2, lines 13-20). Mauvais-Jarvis et al. teach that the anti-estrogen drug, **4-hydroxytamoxifen,** is useful for treating disease of the breast without harmful side effects. (column 3, lines 52-55). Mauvais-Jarvis et al. illustrate the effective amount **4-hydroxytamoxifen and triethanolamine** (a penetration enhancer) utilized in a gel formulation. (column 3, table).

Oden teaches triethanolamine is a penetration enhancer. (column 7, lines 7-10).

Oden reference is provided as an extrinsic evidence show that triethanolamine utilized by Mauvais-Jarvis et al. is a penetration enhancer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragavan et al. (U.S.Patent No. 5,993,856) of record.

Ragavan et al. teach a micro or nanoparticulate drug formulation for topical administration comprising danazole or anticancer drug, anti-proliferative drug in an effective amount formulated in foams, suspension, solution, ointment and cream. (abstract, claims particularly, claims 31-33, Examples 1-3, column 3, lines 10-15). Ragavan et al. teach that **sorbitan esters** and **triethanolamine** (penetration enhancers) can be employed in the formulation. (column 4, lines 4-16). Ragavan et al.

teaches that the microparticle danazol comprises 10mg/day, 25mg/day, 50mg/day. (Example 3). These dosages are within and/or overlap Applicant's preferred danazol dosage rage in the specification on page 9, under dosage. Ragavan et al. illustrate 1mg gel formulation comprising microparticulate formulation of danazol in Examples 1 and 2. Ragavan et al. illustrate that danazole concentrations of 1mg/300g rat were administered and danazol concentrations of 100mg /50kg were administered to women. (table 1). These dosages are within Applicant's dosage range of danazol in the specification page 9. Ragavan et al. Teach that the formulation provides significantly diminished side effects with increased bioavailability and comport. (column 3, lines 15-20).

Ragavan et al. do not illustrate the danazole formulation with triethanolamine or sorbitan esters, the formulation providing relief from disease or disorders of the breast and the property of the carrier capable of delivering the drug to the breast tissue and to promote delivery of the drug across the stratum corneum.

It would have been obvious to one of ordinary skill in the art to formulate danazole with standard excipients such as triethanolamine or sorbitan esters because Ragan et al. teach that these excipients are routinely employed with danazole and they are well known standard excipients. One of ordinary skill in the art would have been motivated to employ any one of standard excipients of danazole formulation taught by Ragavan et al. with a reasonable expectation of successfully formulating danazole formulation providing significantly diminished side effects with increased availability and comfort as taught by Ragan et al. Applicants' recitation in claims 1 and 9 of an

intended use of treating benign diseases of the breast and to relief from disease or disorders of the breast do not represent a patentable limitation since such fails to impart any physical limitation to the composition since the prior teaches same formulation comprising the same active agent with the same "effective amount" as claimed by Applicants. Further, the limitation of the carrier "capable" of delivering the drug for the breast tissue, it is noted that the carriers or excipients employed by Ragan et al. is the same "penetration enhancer" as required by claim 1. Therefore, the same compounds cannot have mutually exclusive properties. Accordingly, the same penetration enhancer taught by Ragan et al. would be "capable" of delivering the drug for the breast tissue and promote delivery of the drug across the stratum corneum upon the contact with skin during an administration step.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 31-33 of U.S. Patent No. 5,993,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a micro or nanoparticulate drug formulation for topical administration comprising danazole or anticancer drug, anti-proliferative drug in an effective amount formulated in foams, tablets and creams and same "effective amounts" of treating a diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast.

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 17 of U.S. Patent No. 6,652,874 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a drug formulation comprising the drug selected from the group consisting of

anticancer drugs, cytotherapeutic drugs, anti-proliferative drugs, and antiviral drugs formulated in micro or naoparticulates with same "effective amounts" of treating a diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast. (see example 3, and instant dosage range in the specification on page 9).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of U.S. Patent No. 6,416,778 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a drug formulation including liquid suspension, hydrogel or topical ointment or a cream comprising the drug particles danazole for regional administration of an effective amount to provide relief from symptoms of a disease or disorder with same "effective amounts" of treating a diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast. (see example 3, and instant dosage range in the specification on page 9).

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed August 13, 2007 have been fully considered but they are not persuasive. Applicants argue that Jarvis does not disclose any penetration

enhancers. This is not found persuasive because Mauvais-Jarvis et al. illustrate the effective amount **4-hydroxytamoxifen and triethanolamine** utilized in a gel formulation. (column 3, table). It is noted that triethanolamine employed by Jarvis is a penetration enhancer as evidenced by Oden. (see above 102 rejection). Applicants argue that Ragavan is silent about including penetration enhancers in the formulation. This is not found persuasive because Ragavan 1 teaches employment of triethanolamine (a penetration enhancer) and sorbitan esters as standard excipients to be included in danazole formulation. It is noted sorbitan esters taught by Ragavan is the same penetration enhancer recited in Applicants specification on page 9. Applicants argue that the formulation disclosed in Ragavan 1 are meant for delivery across mucosal membrane where drug is relatively contained with a reproductive blood barrier so that effective levels can be achieved throughout the region but without systemic levels being achieved. This is not found persuasive because the instant claims are drawn to a "formulation". Therefore, the intended purpose of the same formulation does not impart any physical limitation to the same formulation generally taught by the reference. Applicants argue that the claimed formulation contain a drug in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue in combination with a penetration enhancer, which is used to promote delivery across the skin to include any excipients that would be effective in functioning as a penetration enhancer. This is not found persuasive because the employment of penetration enhancers with danazole composition is well taught by the reference. These penetration enhancers are standard excipients well known by the reference. The

excipients such as triethanolamine is a well known "penetration enhancer" as required by claim 1; the excipients such as sorbitan ester is the same penetration enhancer employed by the Applicants. Accordingly, the same penetration enhancers required by claims cannot have mutually exclusive properties. Therefore, these excipients would too have capability of delivering the drug to the breast tissue and promotes delivery across the skin upon the content of skin during administration step.

Applicants argue that Ragavan I (U.S.Patent No.5,993,856), Ragavan 2 (U.S. Patent 6,652,874), and Ragavan 3 (U.S.Patent No. 6,416,778), do not define a formulation comprising a drug in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue and does not define a formulation comprising a drug and a penetration enhancer to promote deliver of the drug across the stratum corneum. Applicants further argues that region as recited in claims of Ragavan is defined a reproductive organ and their surrounding environs such as mucosal membranes not to deliver across the skin. This is not found persuasive because claims in the instant Application and the patented claims are drawn to the same formulation comprising the same active agent, danazole, the same micro or nano particulates for the topical administration. Therefore, there is a great overlap in the actual content of ingredients in the formulation. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, all the components in instant claims are broadly encompassed by the patented claims. Accordingly, the same

composition comprising the same components taught by the Ragavans would promote delivery accross the skin upon the contact. Applicants argue that there is no motivation for one of ordinary skill in the art to modify the formulations claimed in Ragavan to include a penetration enhancer as claimed. This is not persuasive because the specific penetration enhancer such as "sorbian esters" and "triethanolamine" are well taught by the Ragavans useful and compatible in such formulation. (column 4, lines 4-16). Applicants argue that independent claim 12 defines a composition for treating endometriosis comprising danazol and a carrier and that danazole which is a STEROID is specifically excluded form the claims of the instant Application. This is not persuasive because specific drugs excluded in instant claim 1 are noted. The drugs to be excludes are a non-steroidal anti-inflammatory or analgesics. There is no mention of a STEROID being excluded by the claims. Further, the instant claim 7, recites utilization of danazol. As such, the claims of the instant Application and the patented claims would have been obvious variations of the other to one of ordinary skill in the art. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 23, 2007